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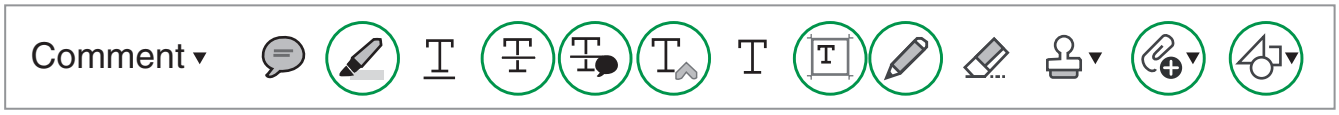

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Clinical experience of magnetic resonance imaging in patients with cardiac pacing devices: unrestricted patient population

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the names, affiliation etc. are ok

Abstract

Background: Magnetic resonance imaging (MRI) in patients with cardiac pacing devices has become available despite previously being considered absolutely contraindicated. However, most institutional safety protocols have included several limitations on patient selection, leaving MRI unavailable for many patients.

Purpose: To evaluate the first 1000 MRI examinations conducted on patients with cardiac pacing devices at ■ [AQ1] for any potential safety hazards and also to evaluate the long-term functionality of the safety protocol in clinical practice.

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Material and Methods: A total of 1000 clinically indicated MRI scans were performed with a 1.5-T MRI scanner according to the safety protocol. The following information was collected from the electronic medical record (EMR): patients' date of birth; sex; pacing device generator model; date of MRI scan; date of the latest pacing device generator implantation; and the body region scanned. The EMR of these patients was checked and especially searched for any pacing device related safety hazards or adverse outcomes during or after the MRI scan.

Results: Only one potentially dangerous adverse event was noted in our study group. In addition, patients with abandoned leads, temporary pacing devices, and newly implanted pacing device generators were scanned successfully and safely.

Conclusion: MRI scans can be performed safely in patients with cardiac pacing devices if the dedicated safety protocol is followed.

Keywords

Magnetic resonance imaging, pacemaker, abandoned pacing leads, safety protocol

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Introduction

The number of patients with cardiac implantable electronic devices (CIEDs), such as pacemakers (PMs), implantable cardiac defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices, is increasing rapidly worldwide due to broad indications for pacing devices and increased life expectancy (1,2). Up to 75% of those patients are estimated to have a clinical indication for magnetic resonance imaging (MRI) over the lifetime of their CIED (3,4).

Previously, cardiac pacing devices have been considered to be an absolute contraindication for MRI because of the potential safety concerns related to interactions of pacing devices and their components with a strong magnetic field as well as gradient and radiofrequency fields. These interactions may cause

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an increase of the pacing rate, inhibition of the pacing, asynchronous pacing, and pacing device reset. The power-on reset may result in the activation of an inhibited pacing mode instead of programmed asynchronous pacing. Electromagnetic interference (EMI) could cause inappropriate inhibition of pacing resulting in asystole (5–11). In addition, MRI may induce currents in the pacing leads and discharge heat into the myocardium, leading to myocardial scar tissue, altered capture thresholds, and therefore impaired function of the pacing device. Under conventional CIED conditions, the induced current in the pacing leads is unlikely to cause myocardial capture, but arrhythmia induction cannot be excluded (12,13). Recent studies have demonstrated that MRI can be performed safely on patients with CIED, although some changes in device parameters have been noted (14–18). However, most previous studies have included limitations on patients' pacing device dependency, age of the pacing device, or body region scanned, and patients with abandoned or epicardial pacing leads have been excluded (14,15,19).

In addition to the increased use of pacing devices in patient care, MRI is also increasingly being used, especially in diagnosing central nervous system, abdominal, and musculoskeletal disorders, tumors, and some cardiovascular diseases (20–22). Therefore, it is important to create a dedicated safety protocol for MRI in patients with cardiac pacing devices.

The aim of this retrospective study was to evaluate the first 1000 MRI examinations conducted on patients with cardiac pacing devices at ■ [AQ2]f Helsinki University Hospital tial safety hazards or clinically signifi effects on the pacing devices during or after the MRI examination, and also to evaluate the long-term functionality of the safety protocol in "real-life" clinical practice.

Material and Methods

Study design

The first 1000 clinically indicated MRI examinations conducted on patients with a cardiac pacing device performed in ■ [AQ3]w Helsinki University Hospital ervational retrospective stud were carried out between Nov 2017. One cardiovascular magnetic resonance (CMR) examination was performed as a part of a clinical study. One MRI examination was not performed because of the noise heard from the pacing device when it entered the magnetic field. This examination was excluded from the study.

All MRI examinations were performed with a Siemens Magnetom Avanto 1.5-T scanner that was updated to Avanto^{fit} (both Siemens Healthcare, Erlangen, Germany) in summer 2013. The Institutional Review Board of Helsinki University Hospital provided approval for this retrospective study.

Safety protocol

The MRI examinations of patients with a CIED were started in ■ [AQ4]in N Helsinki University Hospital to the safety protocol develop etween the Department of C ent of Radiology. This safety protocol incorporated common elements from the previously published protocols and has been described in detail in a prior publication (23). The safety protocol has been updated thereafter according to the lean way of thinking after practical experiences. The safety protocol is presented in Figs. 1 and 2 and described below.

The safety protocol involves procedures for MRI examination in patients with a CIED, including PMs, ICDs, and CRT devices, both MR-conditional and MR-unsafe cardiac pacing devices, without limitations on patients' pacing dependency or the body region to be scanned. According to the safety protocol, a radiologist subspecialized in the field of imaging concerns evaluates the need for an MRI examination after receiving the referral for MRI examination from a requesting physician. If MRI is considered the imaging method of choice, the MRI examination time is scheduled to at least six weeks after the pacing device installation unless there is an urgent clinical need for an RI examination. Patients with an urgent clin- for an earlier MRI examination are scanned according to the same safety protocol as other patients. If the patient has abandoned pacing leads, the cardiologist evaluates the pacing system compatibility for MRI beforehand and enters the imaging decision in the electronic medical record (EMR).

On the day of the MRI examination, before the scan, the CIED is evaluated and programmed for MRI by a cardiologist at the PM policlinic or at the Department of Radiology. During the MRI scan, patients are monitored with electrocardiography (ECG) and pulse oximetry. Patients are also monitored with a camera and asked to report immediately any torque or heating sensation, pain, palpitation, or any other unusual symptoms during imaging. In case of an emergency, a cardiac defibrillator with temporary cardiac pacing feature is immediately available and the personnel at the Department of Radiology are trained to start the resuscitation and to use the defibrillator. The hospital resuscitation team and a cardiologist are called by phone and are immediately available. After the MRI examination, the cardiologist interrogates and re-programs the pacing device back to its original

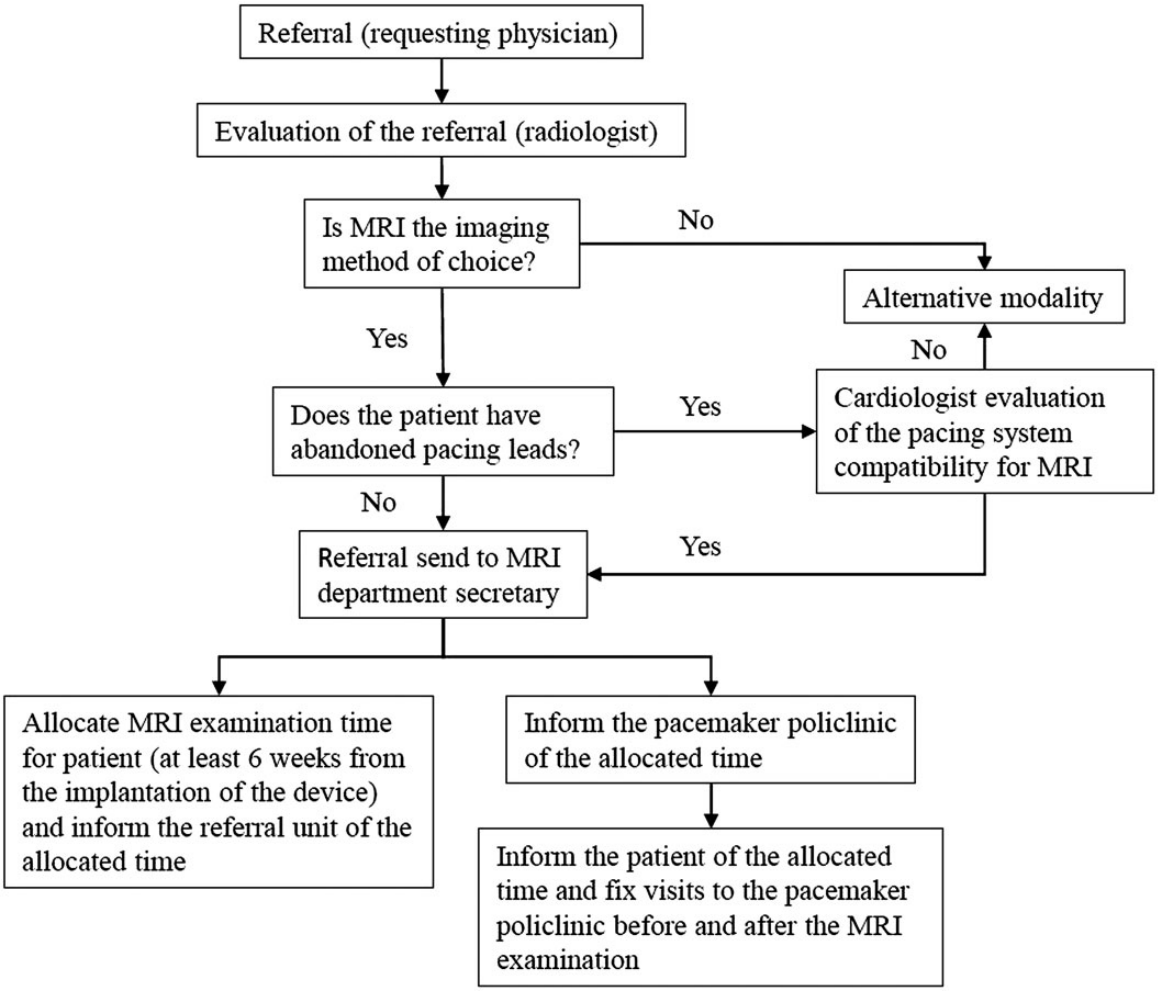

Fig. 1. Evaluation before MRI examination.

settings at the PM policlinic or at the Department of Radiology.

The safety protocol has been modified to this form after some experience of MRI in patients with cardiac pacing devices. According to the original safety protocol, each referral was also evaluated beforehand by a cardiologist. Currently, this is necessary only when the patient is known to have any abandoned pacing leads. In the early phase, the radiologist and physicist were supervising the MRI examination in addition to the radiographer performing the MRI scan. In addition, a cardiologist was present during the MRI scan, whenever the cardiac pacing device was not MR-conditional. After 61 MRI scans without any adverse effects, the cardiologist was no longer required to be present during the MRI scan but to be available if requested. After some more experience in 2016, the radiologist and physicist were not required to attend the MRI scan but to be available if requested. A radiologist has carried a dedicated phone since this decision.

After six months of experience with MRI examinations in patients with pacing devices, the cardiologists stopped entering the exact measured pacing device parameters in the EMR; instead, any clinically relevant changes in the parameters before and after the MRI examination were briefly described. After 3.5 years of experience in July 2015, the one-month routine CIED controls were stopped because no adverse effects on the pacing devices were detected.

According to the safety protocol, it is also possible to perform an MRI scan on a patient with CIED in an emergency case. Most of these scans are performed during the daytime within regular office hours. If the patient's condition is potentially lethal or the patient is at high risk of being paralyzed and needs acute treatment, MRI scans can be performed at any hour. Outside office hours, the senior radiology consultant on duty decides whether an emergency MRI is the imaging method of choice and is present at the MR unit until the emergency scan is completed.

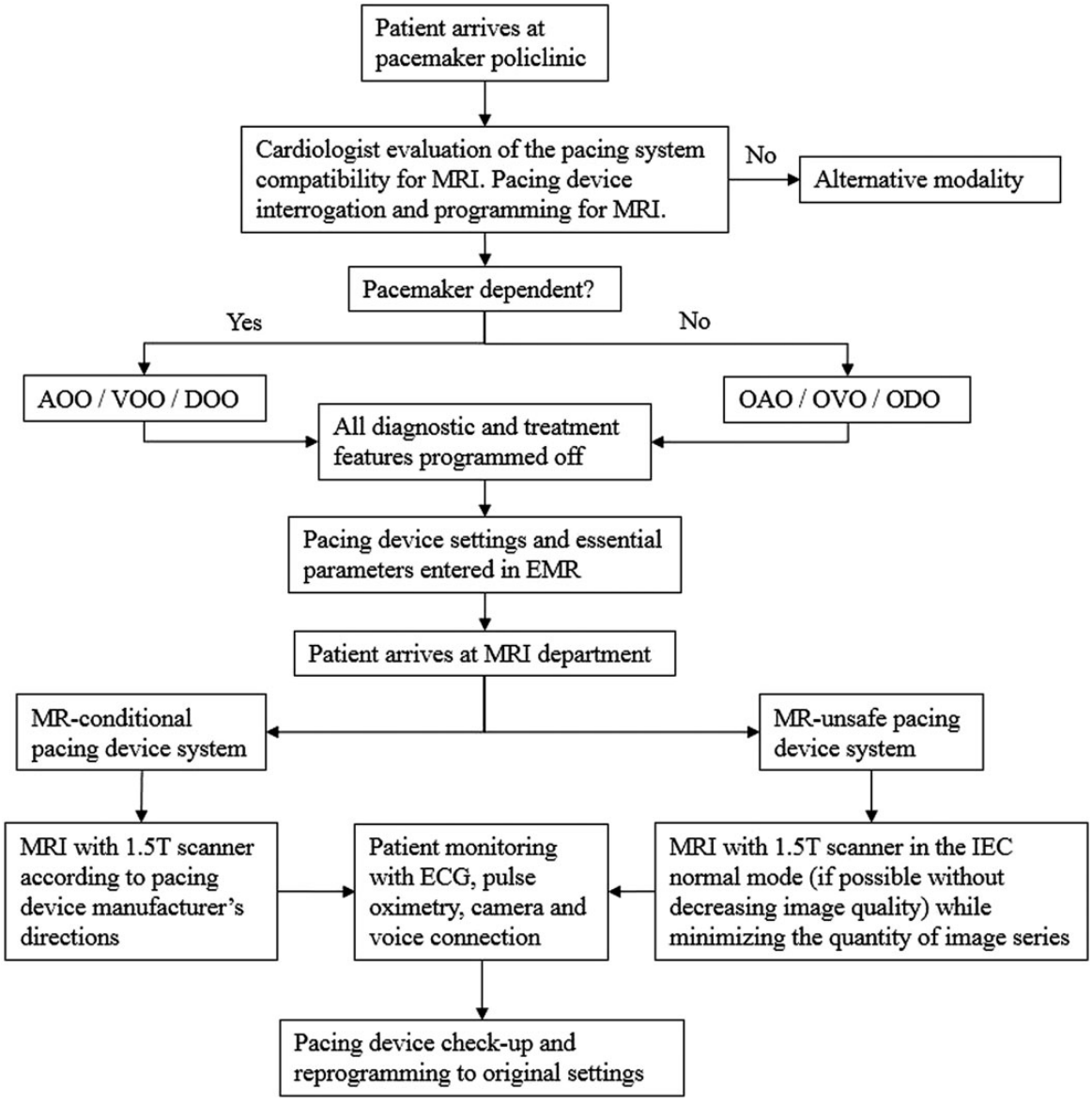

Fig. 2. Procedures before, during, and after the MRI examination. AOO/VOO/DOO, asynchronous pacing modes for atrial/ventricular/dual chamber systems, respectively; ECG, electrocardiography; EMR, electronic medical record; IEC, International Electrotechnical Commission; MR, magnetic resonance; MRI, magnetic resonance imaging; OAO/OVO/ODO, pacing inhibited modes for atrial/ventricular/dual chamber systems, respectively.

Before the MRI examinations, the cardiologist on duty programs the CIED for MRI, and after the scan, reprograms the CIED back to its original settings.

Analysis of data

This study was approved by the local institutional review board. The following information was collected from the EMR: patients' date of birth; sex; pacing device generator model; date of MRI scan; date of the latest pacing device generator implantation; and the body region scanned. The EMR of these patients was checked and searched in particular for any pacing device-related safety hazards or adverse outcomes during or after the MRI scan, such as generator failure, power-on reset, clinically relevant changes in the pacing threshold or sensing that require system revision or programming changes, unexpected battery depletion, inhibition of pacing, patient-reported events, such as discomfort, pain, a warm sensation in the location of the device, and palpitation. Furthermore, also the presence of possible abandoned pacing leads was searched for via the EMR.

Data were analyzed with SPSS (released 2013, IBM SPSS Statistics for Windows, Version 22.0; IBM Corp., Armonk, NY, USA).

Results

A total of 1000 MRI examinations were completed on 793 adult patients with a cardiac pacing device (465 men, 58.6%). The mean age and standard deviation of the patients at the time of MRI examination was 69.5 ± 14.0 years (age range = 18–97 years).

From the first 1000 MRI scans of patients with a CIED, 869 scans (86.9%) were performed on patients having a conventional cardiac PM, 61 scans (6.1%) on patients having an ICD, 39 scans (3.9%) to patients having a CRT with defibrillator (CRT-D) device, and 31 scans (3.1%) to patients having a CRT with PM (CRT-P) device (Table 1). Of these, 139/869 (16%), 16/61 (26.2%), 8/39 (20.5%), and 0/31 (0%) examinations were performed on patients carrying an MR-conditional PM, ICD, CRT-D, or CRT-P device, respectively. The MRI compatibility data of two PMs were missing.

All the scanned cardiac pacing devices, except one, were implanted in 2003 or later and manufactured by the following companies: St. Jude Medical = 56%; Biotronik = 21.4%; Medtronic = 15.3%; Boston Scientific = 6.1%; Guidant = 0.6%; and Vitatron = 0.5%. The manufacturer of one PM was missing. One MRI examination was performed on a patient with a very old non-adjustable cardiac PM installed in 1986. Furthermore, the study group contained two patients with a subcutaneous ICD (S-ICD) device (Boston Scientific Emblem) and two patients with a leadless pacing device (Medtronic Micra). One MRI examination was interrupted because of the noise heard from the PM when entering the magnetic field (Medtronic Maximo 2 CRT-D device). In our study population, one CMR examination was interrupted because of the artifacts caused by the CRT-D device.

Table 1. Number of pacing device types.

Pacing device type	MRI compatibility	Frequency (n (%))
PM	MR-unsafe	728 (83.8)
	MR-conditional	139 (16.0)
	Missing	2 (0.2)
	Total	869 (100.0)
ICD	MR-unsafe	45 (73.8)
	MR-conditional	16 (26.2)
	Missing	0 (0.0)
	Total	61 (100.0)
CRT-D	MR-unsafe	31 (79.5)
	MR-conditional	8 (20.5)
	Missing	0 (0.0)
	Total	39 (100.0)
CRT-P	MR-unsafe	31 (100.0)
	MR-conditional	0 (0.0)
	Missing	0 (0.0)
	Total	31 (100.0)

PM, pacemaker; ICD, implantable cardiac defibrillator; CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy with pacemaker; MR, magnetic resonance.

On average, the time from pacing device generator implantation to the MRI scan was 1180 ± 1002 days. The date of the generator implantation was missing in eight cases. The MRI scan was conducted on 24 patients with a newly implanted cardiac pacing device (<6 weeks, range = 0–41 days) due to an urgent clinical need for the imaging. Eleven of these patients had a temporary cardiac pacing system with externalized permanent active-fixation PM lead connected to a permanent PM generator and the generator was taped onto the chest skin. Six of these "temporary-permanent" generators were MR-unsafe and the data related to MRI compatibility were missing in one case. All these scans were performed without any adverse events.

Two or more MRI examinations were performed on 151 patients. One patient went through as many as eight MRI examinations. Ten of these patients had their pacing device generators changed between the repeated MRI examinations and one of these patients had the pacing device generator changed twice between the examinations. No unexpected battery depletion after the MRI was detected. The generator changes were due to an elective replacement time (n = 7) or an infection (n = 2). One pacing device generator was changed due to a back-up mode caused by radiotherapy. One pacing device generator change was done because of a device upgrade from a temporary pacing system to a permanent pacing system.

In 57 MRI examinations, the patients had two body regions scanned in the same visit. Altogether 1057 body regions were scanned at 1000 MRI examinations (Table 2). The spine was the most scanned body region (n = 326, 30.8%), followed by the head (n = 229, 21.7%), abdomen (n = 181, 17.1%), and cardiovascular examination (n = 144, 13.6%).

In addition, 22 MRI examinations were completed of 17 patients with an abandoned pacing lead without any adverse effects. One of these patients had an abandoned epicardial pacing lead that was cut to <5 cm in length. Two of these patients had two cardiac pacing devices: one abandoned non-functional pacing system with leads attached and one fully functional cardiac pacing device system with leads. All the other abandoned pacing leads were capped and without visual damage on chest X-ray; the insulation of leads was evaluated to be undamaged.

Table 2. Number of magnetic resonance imaging examinations performed for different body regions.

Body regions scanned	Frequency (n (%))
Spine	326 (30.8)
Head	229 (21.7)
Abdomen	181 (17.1)
Heart	144 (16.3)
Extremity or joint	131 (12.4)
Pelvis	19 (1.8)
Thorax	15 (1.4)
Other	12 (1.1)
Total	1057 (100.0)

In the 1000 MRI examinations performed, there was only one potentially dangerous adverse effect on the pacing device detected. In this case, the PM fell in to the elective replacement indicator (ERI) mode due to temporarily programmed high output voltage. As a consequence, the PM programmed to asynchronous pacing mode for dual chamber system (DOO) was changed to ventricular pacing in the inhibited mode (VVI), which is the inherent ERI mode with this particular PM model (Medtronic Kappa KSR 401). This patient was pacing device-dependent. Another patient, with the Medtronic Kappa KDR 401 PM model, fell into full electrical reset mode with VVI 65/min pacing mode due to electromagnetic interference. After the MRI scan, the PM was undamaged and it was reprogrammed to the previous mode. This patient was not pacing device-dependent. One patient had a noise reversion notification during the MRI from the pacing device system St. Jude Medical Unify Quadra CD3251-40 Q CRT-D. Noise reversion is an algorithm that causes the pacing device to automatically change the pacing mode to asynchronous pacing if it is programmed to synchronous mode. Noise reversion can be caused by EMI. The scanning was interrupted for a moment, the pacing device was re-programmed, and the scan was completed safely. Three patients reported subjective symptoms during the MRI scan (feeling ill after the MRI examination, sensing coldness at the pacing device generator area, or chest pain), but most likely these symptoms were not related to the MRI examination. One S-ICD device's alarm system was most likely damaged at MRI. This damage concerns only the voice of the S-ICD device's beeper system, otherwise the alarm system is fully functional and can be followed remotely. This is an inherent problem with Boston Scientific ICDs according to vendor information (24).

In this study group, 105 (10.5%) emergency MRI examinations were performed, of which 19 were performed outside regular office hours. All these scans were completed safely.

Discussion

In this study, we investigated the use of the dedicated safety protocol for an MRI in patients with a CIED in a "real-life" setting. Most previous studies on MRI in patients with a CIED have included limitations on patients' pacing device dependency, age of the pacing device, or body region scanned, and patients with abandoned or epicardial pacing leads have been excluded. In the real world, there are many patients with a CIED who do not meet these criteria but need an MRI. It is estimated that >8 million people worldwide have implanted cardiac devices which do not meet the MR-conditional criteria (11).

According to our large patient dataset and clinical experience, the MRI examinations can be performed safely on patients with CIED without limitations on pacing device type (PM/ICD/CRT-D/CRT-P), pacing device MRI compatibility (MR-conditional/MR-unsafe), patients' pacing device dependency, or the body region scanned if the dedicated safety protocol is followed. Our finding is supported by previous studies (14,15,19,23,25–27). The Heart Rhythm Society (HRS) published an expert consensus statement on MRI in patients with CIED in 2017 (28). Our safety protocol presented here mostly adheres to HRS consensus statement with some minor exceptions. First, we have scanned also patients with abandoned leads, as presented in this manuscript. Second, a cardiologist is not in attendance with pacing device-dependent patients but immediately available per phone. Third, the pacing device is checked immediately after the MRI examination and one year after the MRI examination, not in 3–6 months after the MRI. The safety protocol described here was improved and simplified according to the lean way of thinking after practical experiences. Before the HRS consensus statement was published in 2017, our safety protocol in its present form had been in active use for almost two years without safety hazards and, in our experience, it is safe and functional. Currently, MRI scans in patients with card devices is part of the everyday routine in ■ [

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One potentially dangerous adverse event was noted when a PM (Medtronic Kappa KSR 401) of a pacing device-dependent patient fell into the ERI mode. Fortunately, EMI did not cause significant inhibition of pacing during this MRI examination. This happened in May 2013. The patient was MRI-scanned patient with a CIED in ■ [A situation could have probably been avoided with different cardiac pacing device settings. After this incident, similar situations have not occurred. In addition, one power-on reset (1/1000, 0.1%) occurred to a non-pacing-dependent patient with Medtronic Kappa 401 PM system. In previous studies, the

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occurrence of power-on resets has been reported to be 0.4–0.6%, which is in line with our results (14,27). In a prior publication, it was noted that older generation Medtronic Kappa PMs (market release before 2002) have a higher risk for power-on reset than other devices during MRI scan (29). This supports our findings.

In our study group, only one MRI examination was not performed because of noise heard from the pacing device when entering the magnetic field. Later on, it was noted that this is a feature of this CIED model; later MRI examinations have been completed successfully of patients with this particular CIED model (Medtronic Maximo 2 CRT-D device).

Abandoned pacing leads have been considered to cause significant risk in MRI on the basis of modeling studies that found abandoned leads to resonate heat energy in radiofrequency fields (30). However, in a recent study, a relatively large number of MRI scans (n = 97) was performed on patients with abandoned pacing leads without safety hazards (26). A few published studies, with a smaller number of patients, on MRI scans in patients with abandoned pacing leads have reported similar findings (31–33). In our patient population, patients with abandoned pacing leads were scanned successfully and safely when a radiologist considered MRI necessary and a cardiologist considered the pacing device system suitable for MRI.

Published institutional safety protocols for MRI in patients with a CIED include limitations on system implant duration before MRI. This is due to plausible lead maturation in a certain time. Occasionally, an urgent MRI is needed and considered necessary regardless of the system implant duration. In our study group, patients with newly implanted (<6 weeks) pacing device generators were scanned successfully without safety hazards. This subgroup included 11 patients with a temporary pacing system who were also scanned successfully without adverse events. To our knowledge, this is the first report regarding MRI examinations performed on patients with an MR-unsafe "temporary-permanent" pacing system. One case report has been published of MRI being conducted safely on a patient after implantation of a "temporary-permanent MR-conditional" pacing system (34).

The limitations of this study should be considered carefully. First and foremost, our data did not include exact pacing device parameters before and after the MRI examination. Because of the changes made to the safety protocol in the early phase, only the cardiologist's clinical interpretation on parameter changes was entered in EMR. In previous studies, clinically significant changes in cardiac pacing device parameters related to MRI have been rare (15,23,25). The data of patients' pacing device dependency or the indications for pacing device implantations were not available. Therefore, we cannot exactly evaluate whether this study group represents the whole population of patients with CIED. A large number of patients in our study group had a pacing device system that had been originally implanted before the EMR was used in our hospital and the data of the electrode models were not available. Due to this lacking information, we categorized pacing devices only according to the pacing devices' generator model to MR-conditional and MR-unsafe devices. This safety protocol has no limitations on pacing device dependency or body region scanned; almost all patients referred for MRI were scanned. However, some patients with visually damaged uncapped leads were not scanned. Almost all CIEDs scanned in our study group were implanted in the year 2003 or after and the results cannot be directly extrapolated to older CIED models. In this study, only a 1.5-T magnetic field strength was used.

In conclusion, if MRI examinations in patients with cardiac pacing devices are performed in a controlled and monitored environment, these can be conducted safely also in an unrestricted patient population, including pacing-dependent patients and patients with MR-unsafe cardiac pacing devices.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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